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09/471,255	12/23/1999	JOSEE HAMEL	55190-012	7195

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EXAMINER
PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
1645	4

DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/471,255	Applicant(s) Hamel et al
	Examiner Portner	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 4, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-16, 18-35, and 38-42* is/are pending in the application.

4a) Of the above, claim(s) *1-15, 21-24, and 26-31* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *16, 18-20, 25, 32-35, and 38-42* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-16, 18-35, and 38-42* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

New Claims 38-42 have been added.
Claim 17, 36 and 37 have been canceled.
Claims 16, 18, 25, 32-35 have been amended.
Claims 16, 18-20, 25, 32-35 and 38-42 which recite the elected invention (SEQ ID NO 2) are under consideration.

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1.A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on **March 4, 2003** has been entered.

Election/Restriction

2. Claims 16, 18, 25 have been amended and new claims 38-42 have been submitted. All of the claims recite the elected invention SEQ ID NO 2, but also recite non-elected inventions (SEQ ID NO 10, 16 and 55). As the instant Application is an RCE, continued prosecution on the finally rejected invention will be considered on the merits herein. Applicant's election with traverse of Group II, (claims 16-20 and 25), SEQ ID NO 2 in Paper No. 16, dated September 19, 2001 was acknowledged and made Final.

3. Newly submitted claims (claims 38-42, and amended claims 16,18, 25, 32-35) which recite SEQ ID NO 10, 16 and 55 are directed to an invention that is independent or distinct from the

originally examined/elected invention for the following reasons: each product represented by a SEQ ID No, and each sequence represents a materially independent and distinct product, which differs in structure, function and effect.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, those portions of claims 16,18, 25, 32-35 and 38-42 are herein withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Applicant asserts that the elected invention is directed to polypeptides of BVH-3 (see Amendment dated March 4, 2003; paragraph bridging pages 3-4).

5. Contrary to Applicant's assertion, the elected invention is SEQ ID NO 2, not all BVH-3 polypeptides, which include specific mutants and variants of BVH-3. Applicant is directed to original paper number 12, page 5, paragraph 7, that defined each polypeptide with a different SEQ ID No as a materially different product. Claims directed to polypeptides with the amino acid sequence represented by SEQ ID NO 10, 16 and 55 are herein withdrawn from consideration.

What is claimed are polypeptides that vary from the reference sequence SEQ ID NO 2 (95% sequence identity), as well as polypeptides that comprise an amino acid sequence of SEQ ID NO 2. None of the claims are required to be limited to "BVH-3" polypeptides as argued by Applicant. While the claims encompass the polypeptides with the amino acid sequence SEQ ID

NO 2, the scope of the claims is far broader than just SEQ ID NO 2, as the claims recite the term "having" which is analogous to the word "comprising", which permits the presence of additional amino acids and molecules, as well as permits differences from the elected polypeptide represented by SEQ ID No. 2, as none of the claims are limited to just the polypeptide of SEQ ID NO 2.

Allowable Subject Matter

6. The allowable subject matter previously indicated is herein withdrawn, in light of new grounds of objection/rejection set forth below. The examiner's reading of the claims has been changed based upon Applicant's statements on the record that the phrase "an amino acid sequence of SEQ ID NO 2" intends to include not only the full amino acid sequence of SEQ ID No. 2, also to encompass fragment portions of SEQ ID NO 2 (see Applicant's response, March 4, 2003, page 4, paragraph 3) which sets forth narrative to define the phrase "full length" to include amino acids 1-1019, as well as portions (fragments, truncated portions of SEQ ID NO 2) represented by amino acids as shown in the instant specification page 53, Table 3.

The originally indicated Allowable subject matter was intended to be for the single polypeptide represented by the amino acid sequence SEQ ID NO 2, but all of the claims, in light of Applicant's clarifying statements, are directed to a plurality of polypeptides that comprise any portion of SEQ ID NO 2, as well as SEQ ID NO 2. Based upon this understanding of the claims, new grounds of rejection are being set forth below.

7. Applicant at page 5, paragraph 4, states "[A]pplicants have rewritten the claims as suggested by the Examiner. Applicants submit that claims 18-20 are now allowable".

8. In response to Applicant's statement, the examiner would like to clarify the record, by stating that the non-elected inventions were requested to be removed. The elected invention is the polypeptide with the amino acid sequence of SEQ ID No 2 and the genus of polypeptides that comprise an amino acid sequence of SEQ ID NO 2; claims 18-20 still recite non-elected inventions, specifically SEQ ID NO 10, 16 and 55. Applicant, in the response dated March 4, 2003, sought to redefine the elected invention to be all BVH-3 polypeptides; the election/restriction never mentioned the term BVH-3 polypeptides, but only set forth independent and distinct inventions based upon SEQ ID Nos, for polypeptides that structurally, and functionally differed one from another, which results in differing effects.

Objections/Rejections Withdrawn

9. Claims 16, 25, 32,34-35 rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, credible and substantial asserted utility or a well established utility, in light of the claims requiring the polypeptide to stimulate an antisteptococcal immune response.

10. Claims 16, 25,32, and 34-35 rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, credible and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, in light of the claims requiring the polypeptide to stimulate an antisteptococcal immune response.

11. Claims 19-20 and 34-35 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, in light of the claims reciting the phrase "at least 95% identity".

12. Claim 16, 19-20 and 25 rejected under 35 U.S.C. 112, second paragraph for reciting non-elected inventions, in light of new grounds of objection set forth below.

Rejections Maintained

13. Claims 16,18, 25, 32-35 and 38-42 as previously applied to claim 32 are rejected under 35 U.S.C. 112, second paragraph, for reciting the phrase "an amino acid sequence of SEQ ID Nos 2", which is a phrase equivalent to "an amino acid sequence chosen from", as the claimed isolated polypeptide is only required to have an amino acid sequence of SEQ ID No 2. This rejection could be obviated by amending the claim to recite --said second polypeptide comprising the amino acid sequence of SEQ ID NO 2--. The phrase " an amino acid sequence" recites the indefinite article "an"; amendment of the claim to recite the term --the-- would bring clarity to the claim invention.

14. Claims 16, 18-20, 25, 32-35 and 38-42, as previously applied to claims 16, 25,32, and 34-35, are rejected under 35 U.S.C. 112, first paragraph (*written description*), as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record in paper number 17, paragraph 12, as previously applied to claims 16-20 and 25.

15. Claims 25, 34-35, 40, 42 are rejected under 35 U.S.C. 112, first paragraph (vaccine scope of enablement),because the specification, while being enabling for the production of a polypeptide consisting of SEQ ID No 2 and use of the polypeptide for the induction of a protective immune response when combined with QuilA, and immunogenic fragments for the induction of antibodies to detect SEQ ID NO 2, does not reasonably provide enablement for the use of any polypeptides that only shares 95 % sequence identity with a second polypeptide that comprises any portion of an amino acid sequence of SEQ ID NO 2 to induce a protective immune response.

16. Claim 16, 18-20, 25, 32-35 and 38-42 are rejected under 35 U.S.C. 102(a) as being anticipated by WO98/18930,(Human Genome Sciences, May 7, 1998, SEQ ID NO 182, 56 and 66), for reasons of record and arguments set forth below.

Please Note: The examiner is reading all of the claims to be directed to isolated polypeptides that are of any length as long as they share the recited degree of sequence identity with a second polypeptide of any length that has an amino acid sequence of SEQ ID NO 2 over the full length of the second polypeptide.

SEQ ID NO 2: ----------

Second polypeptide: ---------- 20aa (an amino acid sequence of SEQ ID NO 2)

Claimed polypeptide: ------^----------********** (* additional amino acids "comprising" language); 19aa identical/1aa differs over full length of second polypeptide (95% identity with second polypeptide)

Response to Arguments

17. The rejection of claims 16,18, 25, 32-35 and 38-42 under 35_U.S.C. 112, second paragraph, for reciting the phrase "an amino acid sequence of SEQ ID Nos 2", which is a phrase equivalent to "an amino acid sequence chosen from", as the claimed isolated polypeptide is only required to have an amino acid sequence of SEQ ID No 2, is traversed on the grounds that SEQ ID No. 2 has been provided in the figures and the sequence listing, the size of the polypeptide is sufficient to raise an immune response and the function of the polypeptide is to raise an immune response.

18. It is the position of the examiner that the claims are unclear with respect to what amino acid sequence of SEQ ID NO 2 is included in the claimed polypeptide, and what additional amino

acids are in association with the sequence selected from SEQ ID NO 2, as the claimed polypeptide need only evidence 95% identity with the second polypeptide, which is not, or need not be SEQ ID No 2, and the second polypeptide must only comprise a portion of the amino acid sequence of SEQ ID NO 2.

The sequence and size of the second polypeptide has not been clearly defined in the instant specification, nor in the claims. The second polypeptide may include all of SEQ ID NO 2 or only a portion of SEQ ID NO 2, but may comprise additional amino acids in combination with the amino acid sequence of SEQ ID No 2 and the claimed polypeptide (claims 16 and 25) need only share 95% sequence identity with the second polypeptide. The isolated polypeptide of claim 18, only comprises an amino acid sequence of SEQ ID No. 2, and is not required to induce an immune response directed against streptococci, and need not evidence any specific biological function. The second polypeptide defines a genus of polypeptides that include variants of SEQ ID NO 2 amino acid sequence based upon Applicant's remarks with respect to support the "full length" polypeptide at page 4, Amendment dated March 4, 2003, paragraph 3, to include all of the amino acids of SEQ ID No 2, as well as fragment portions of SEQ ID NO 2 defined by a range of amino acids. The rejection under 35 U.S.C. 112, second paragraph was not made over SEQ ID NO 2, but over what the second polypeptide sequence is that comprises "an amino acid sequence of SEQ ID NO 2", relative to the claimed polypeptide which may structurally differ from the second polypeptide and from SEQ ID NO. 2.

The amino acid sequence of the second polypeptide is unclear, as it does not have any specific sequence in it other than the amino acid sequence that will stimulate an antistreptococcal immune response, which could be an epitope of 8 amino acids, but what the additional amino acids that are included in the second polypeptide are, are not clearly and distinctly claimed, nor is

the sequence for the claimed polypeptide that shares 95% sequence identity with the second polypeptide, the sequence of the claimed polypeptide has having not been clearly defined through reference to a second polypeptide that has not been clearly defined.

Despite the fact that Applicant's specification clearly defines what SEQ ID NO 2 is, and that SEQ ID No 2 is able to induce an antistreptococcal immune response, the claimed polypeptide is not a polypeptide that consists of a sequence of amino acids represented by SEQ ID No. 2; Applicant's arguments are not commensurate in scope with the instantly claimed invention.

The rejection of claims 16,18, 25, 32-35 and 38-42 under 35_U.S.C. 112, second paragraph, could be obviated by amending the claim to recite: "said second polypeptide" [having an] --**comprising the**-- "amino acid sequence of SEQ ID NO 2". The phrase " an amino acid sequence" recites the indefinite article "an"; amendment of the claim to recite the term --the-- would bring clarity to the claimed invention.

19. The rejection of claims 16, 18-20, 25, 32-35 and 38-42, as previously applied to claims 16, 25,32, and 34-35, under 35 U.S.C. 112, first paragraph (*written description*), as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is traversed on the grounds that: "Applicants have amended the claims to recite that the biological activity of eliciting an immune response."

20. It is the position of the examiner that claims 18-20 do not recite the biological activity used to traverse this rejection.

Additionally, independent claims 16 and 25 are directed to amino acid sequences that encode polypeptides that correspond to sequences from other sources, mutated sequences, sequences that have a recited degree of identity (similarity, homology), analogs and derivatives of SEQ ID No 2 and is only required to comprise a single immunogenic epitope of SEQ ID NO 2; the claimed genus of polypeptide has not been described. In support of this position the examiner is providing sequence alignments that read on Applicant's claims, but are not S. pneumonia polypeptides:

a. Prominin-like protein (fragment) shares 7 out of 8 amino acids from position 6 to position 13 of SEQ ID No. 2, a sequence of amino acids that could induce an immune response to streptococcus, but is a polypeptide from Zebrafish.

b. Merizoite surface protein 1 precursor shares 5 out of 6 amino acids from position 842 to 847 of SEQ ID No. 2, a sequence of amino acids that could induce an immune response to streptococcus, but is a polypeptide from Plasmodium falciparum.

c. Spore cortex-lytic enzyme precursor shares 7 out of 8 amino acids from position 78 to 85; and 6 out 7 amino acids from position 114 to 120 of SEQ ID No. 2, a sequence of amino acids that could induce an immune response to streptococcus, but is a polypeptide from Clostridium perfringens.

The claimed invention set forth in independent claims 16 and 25 only require the claimed polypeptide to evidence 95% sequence identity with a second polypeptide, the sequence of the second polypeptide not being defined by any other specific amino acid sequence than one that is an amino acid sequence of SEQ ID NO 2 that is immunogenic. The size, sequence and overall

biological function of the second polypeptide have not been described, other than it comprises an immunogenic epitope that will induce an immune response reactive with Streptococci. None of these sequences, other than SEQ ID NO 2, and SEQ ID NO2 minus the N-terminal or leader sequences, or ~~specific~~ specifically disclosed, but not claimed fragments of SEQ ID NO 2, meet the written description provision of 35 U.S.C. 112, first paragraph.

The written description rejection made it clear that SEQ ID No 2 has been clearly described, but did not provide written descriptive support over the full scope of the claimed genus of polypeptides. The rejection is maintained for reasons of record.

21. The rejection of claims 25, 34-35, 40, 42 under 35 U.S.C. 112, first paragraph (vaccine scope of enablement), because the specification, while being enabling for the production of a polypeptide consisting of SEQ ID No 2 and use of the polypeptide for the induction of a protective immune response when combined with QuilA, and immunogenic fragments for the induction of antibodies to detect SEQ ID NO 2, does not reasonably provide enablement for the use of any polypeptides that only shares 95 % sequence identity with a second polypeptide that comprises any portion of an amino acid sequence of SEQ ID NO 2 to induce a protective immune response is traversed on the grounds that: [A]ccording to another aspect, there are provided vaccine compositions comprising one or more streptococcus polypeptides of the invention in admixture with a pharmaceutically acceptable carrier diluent or adjuvant."

22. It is the position of the examiner that the scope of enablement (vaccine polypeptides) was made over the scope of the elected/claimed invention directed to polypeptides that have at least 95% identity along the full length of a second polypeptide, the second polypeptide having an amino acid sequence held in common with SEQ ID NO 2. A genus of second polypeptides have

not been described that evidence the induction of a protective immune response, no less a genus of polypeptides that share at least 95% identity with the second polypeptide that also induce a protective immune response.

Applicant's arguments directed to compositions that comprise a plurality of streptococcus polypeptides is not commensurate in scope with the claimed/elected invention and does not address the lack of written description of a genus of protective polypeptides that will induce a protective immune response upon administration to an individual. The scope of enablement rejection is maintained for reasons of record.

23. The rejection of claims 16, 18-20, 32 and 38-39,41 are rejected under 35 U.S.C. 102(a) as being anticipated by WO98/18930,(Human Genome Sciences, May 7, 1998, SEQ ID NO 182, 56 and 66), is traversed on the grounds that the polypeptides of WO98/18930 would not elicit an immune response, specifically a region that lacks "immunity inducing capability".

24. It is the position of the examiner that claims 16, 18-20, 32 and 38-39,41 do not require the claimed polypeptide to induce protective immunity against challenge, but only elicit an antibody immune response. The polypeptides of WO98' are polypeptides of 129, 136 and 447 amino acids in length; clearly these polypeptides would induce an antibody immune response directed against streptococcus. Applicant's arguments are not commensurate in scope with the instantly claimed inventions, wherein the claimed polypeptides may comprise any portion of SEQ ID NO 2, through the recitation of the phrase "an amino acid sequence of SEQ ID NO 2.

Additionally, it is the position of the examiner that none of the claimed polypeptides are required to comprise the essential C-terminal hyper variable region without any changes in the epitopes that induce the protective immune response argued.

New Claims/New Claim Limitations/New Grounds of Rejection

Claim Objections

25. Claims 16, 18-20, 25, 32-35 and 38-42 are objected to because of the following informalities: The claims recite non-elected inventions. Appropriate correction is required.

26. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

27. Claims 32-33, 34-35 and 41-42 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32-33 recite the indefinite article "an"; the claims could be made definite through amendment of the claim to recite --the--.

Claim 34 recites the phrase "wherein the polypeptide lacks an N-terminal methionine residue" and depends from claim 25, that does not require, nor define the claimed polypeptide to comprise "an N-terminal methionine". The phrase recited in claim 34 lacks antecedent basis in claim 25 from which it depends. How many N-terminal methionines does the polypeptide of claim 25 comprise? While SEQ ID NO 2 comprises an N-terminal methionine residue, the second polypeptide is not defined to comprise a an N-terminal methionine residue and the claimed polypeptide need only comprise a sequence of 95% sequence identity with the second polypeptide that may or may not comprise an N-terminal methionine residue. What the claimed polypeptide of claim 25 comprises is unclear, therefore it is not clear that claim 34 is further limiting of claim 25 from which it depends.

Claim 35 recites the phrase "wherein the secretory amino acid sequence of the polypeptide is deleted" and depends from claim 25, that does not require, nor define the claimed polypeptide to comprise a "secretory amino acid sequence". The phrase recited in claim 35 lacks antecedent basis in claim 25 from which it depends. While SEQ ID NO 2 comprises a secretory amino acid sequence, the second polypeptide is not defined to comprise a secretory amino acid sequence and the claimed polypeptide need only comprise a sequence of 95% sequence identity with the second polypeptide that may or may not comprise a secretory amino acid sequence. What the claimed polypeptide of claim 25 comprises is unclear, therefore it is not clear that claim 35 is further limiting of claim 25 from which it depends.

Claims 41-42 recite the phrase "at least 99% identity along the full length of said second polypeptide". The full length and amino acid sequence are unclear as the size and sequence of the second polypeptide are not set forth in the claims. The polypeptide that evidences at least 99% identity with the second polypeptide is also not distinctly claimed as the second polypeptide to which the claimed polypeptide must have 99% identity has not been clearly defined.

Conclusion

28. This is a non-final action.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

May 12, 2003

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